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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/525,292-Conf. #6073 |
| | Filing Date | October 27, 2005 |
| | First Named Inventor | Hans-Juergen KRAUSE |
| | Art Unit | 1700 |
| | Examiner Name | Not Yet Assigned |
| Total Number of Pages in This Submission | Attorney Docket Number | BBI-185US |

| ENCLOSURES (Check all that apply) | | |
|--|--|--|
| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO Form SB/08; Copies of Thirteen (13) References; Certificate of Mailing; Return Receipt Postcard |
| <div>Remarks</div> | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|--|----------|--------|
| Firm Name | LAHIVE & COCKFIELD, LLP | | |
| Signature | | | |
| Printed name | Maria Laccotripe Zacharakis, Ph.D., J.D. | | |
| Date | October 30, 2006 | Reg. No. | 56,266 |

| | |
|---|--|
| I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. | |
| Date: October 30, 2006 | Signature: (Maria Laccotripe Zacharakis, Ph.D., J.D.) |

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Dated: October 30, 2006

Signature: 

(Maria Laccotripe Zacharakis, Ph.D., J.D.)

Docket No.: BBI-185US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hans-Juergen Krause *et al.*

Application No.: 10/525,292

Confirmation No.: 6073

Filed: October 27, 2005

Art Unit: 1700

For: FORMULATION OF HUMAN ANTIBODIES
FOR TREATING TNF-ALPHA
ASSOCIATED DISORDERS

Examiner: Not Yet Assigned

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT (IDS)

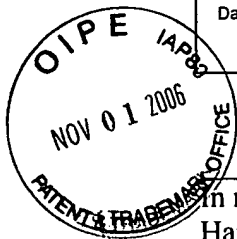
Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicants have not submitted copies of U.S. patents. Applicants submit herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information



as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. BBI-185US.

Dated: October 30, 2006

MLZ/JAM/mch

Respectfully submitted,

By 

Maria Laccotripe Zacharakis, Ph.D., J.D.

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PTO/SB/08a/b (07-06)

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| | | | Application Number | 10/525,292-Conf. #6073 | |
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| | | | First Named Inventor | Hans-Juergen KRAUSE | |
| | | | Art Unit | 1700 | |
| | | | Examiner Name | Not Yet Assigned | |
| Sheet | 1 | of | 1 | Attorney Docket Number | BBI-185US |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| | A1* | US-5,945,098 | 08-31-1999 | Sarno et al. | |
| | A2* | US-6,024,938 | 02-15-2000 | Corbo et al. | |
| | A3* | US-6,090,382 | 07-18-2000 | Salfeld et al. | |
| | A4* | US-6,171,586 | 01-09-2001 | Lam et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|--------------------------|---|-----------------------------------|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | B1 | EP-0486526-B1 | 05-27-1992 | Peptide Technology Ltd. | | |
| | B2 | WO-97/04801-A1 | 02-13-1997 | Genentech Inc. | | |
| | B3 | WO-98/22136-A2 | 05-28-1998 | Boehringer Mannheim GmbH | | |
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| | B5 | WO-01/47554-A1 | 07-05-2001 | Chugai Pharmaceutical Co. Ltd. et al. | | Abstr. |
| | B6 | EP-1174148-A1 | 01-23-2002 | Yamanouchi Pharmaceutical Co. Ltd. | | |
| | B7 | WO-02/12502-A2 | 02-14-2002 | Centocor, Inc. | | |
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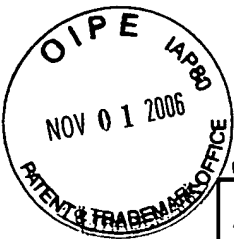
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| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-----------------------|---|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | C1 | Cleland, Jeffrey L. et al, "A Specific Molar Ratio of Stabilizer to Protein is Required for Storage Stability of a Lyophilized Monoclonal Antibody," <i>Journal of Pharmaceutical Sciences</i> , Vol. 90(3):310-321 (2001) | | |
| | C2 | Hillgren, Anna et al, "Protection mechanism of Tween 80 during freeze-thawing of a model protein, LDH," <i>International Journal of Pharmaceutics</i> , Vol. 237:57-69 (2002) | | |
| | C3 | Holt, Lucy J. et al, "Domain antibodies: proteins for therapy," <i>Trends in Biotechnology</i> , Vol. 21(11):484-490 (2003) | | |
| | C4 | International Search Report for Application No. PCT/IB03/04502, dated May 26, 2004 | | |
| | C5 | International Preliminary Examination Report for Application No. PCT/IB03/04502, dated February 14, 2005 | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| | | | |
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| Examiner Signature | | Date Considered | |
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Application No. (if known): 10/525,292

Attorney Docket No.: BBI-185US

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Maria Laccotripe Zacharakis, Ph.D., J.D.

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56,266
Registration Number, if applicable

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